

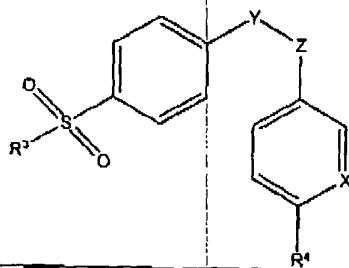
Serial No. 09/904,098
Attorney Docket No. 3351/2/US
HDP Ref. No. 6794-100135/US

Amendments to the Claims

The following listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims

1. (currently amended) A pharmaceutical composition suitable for topical administration to an eye, the composition comprising a selective COX-2 inhibitory drug or a salt or prodrug thereof in a concentration effective for treatment and/or prophylaxis of a COX-2 mediated ophthalmic disorder in the eye, and at least one ophthalmically acceptable excipient ingredient that reduces the rate of removal of the composition from the eye by lacrimation such that the composition has an effective residence time in the eye of about 2 to about 24 hours when topically administered to the eye of a patient, wherein the selective COX-2 inhibitory drug is a compound having the formula:



where R³ is a methyl, amino or imide group, R⁴ is hydrogen or a C₁₋₄ alkyl or alkoxy group, X is N or CR⁵ where R⁵ is hydrogen or halogen, and Y and Z are independently carbon or nitrogen atoms defining adjacent atoms of a five- to six-membered ring that is unsubstituted or substituted at one or more positions with oxo, halo, methyl or halomethyl groups; and the composition ~~being~~ is in the form of an in situ gellable solution, suspension or solution/suspension having ophthalmically compatible pH and osmolality and containing a carrageenan.

Claims 2-3 (canceled).

Serial No. 09/904,098
Attorney Docket No. 3351/2/US
HDP Ref. No. 6794-100135/US

4. (currently amended) The composition of Claim ~~[[3]]~~ 1 wherein the five-to six-membered ring is a ring selected from the group consisting of: cyclopentenone, furanone, methylpyrazole, isoxazole, and a pyridine ring substituted at no more than one position.

5. (original) The composition of Claim 1 wherein the selective COX-2 inhibitory drug is selected from the group consisting of: celecoxib; deracoxib; valdecoxib; rofecoxib; etoricoxib; 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one; (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid; and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl) phenyl]-3-(2H)-pyridazinone.

Claims 6-7 (canceled).

8. (previously presented) The composition of claim 1 that comprises about 0.01% to about 50% weight/volume of the selective COX-2 inhibitory drug.

9. (previously presented) The composition of claim 1 that comprises about 0.1% to about 20% weight/volume of the selective COX-2 inhibitory drug.

Claims 10-11 (canceled).

12. (previously presented) The composition of Claim 1 that (a) comprises about 0.1% to about 6.5% by weight of one or more lightly cross-linked carboxyl-containing polymers, (b) has a pH of about 3 to about 6.5 and an initial viscosity, when administered to the eye, of about 1000 to about 30,000 cPs, and (c) gels on contact with tear fluid having a pH of about 7.2 to about 7.4.

13. (original) The composition of claim 12 wherein the carboxyl-containing polymer is polycarbophil.

Serial No. 09/904,098
Attorney Docket No. 3351/2/US
HDP Ref. No. 6794-100135/US

14. (previously presented) The composition of claim 1 that comprises about 0.1% to about 2% by weight of a polysaccharide that gels when it contacts an aqueous medium having the ionic strength of tear fluid.

15. (original) The composition of claim 14 wherein the polysaccharide is gellan gum.

16. (previously presented) The composition of Claim 1 that comprises about 0.2% to about 3% by weight of a polysaccharide that gels on contact with calcium ions, and about 1% to about 50% of a water-soluble film-forming polymer.

17. (original) The composition of Claim 16 wherein the polysaccharide is selected from gellan gum, alginate gum, xanthan gum and chitosan.

18. (previously presented) The composition of Claim 1 that comprises an ophthalmically acceptable mucoadhesive polymer.

19. (previously presented) The composition of Claim 1 that is a solution or solution/suspension wherein the selective COX-2 inhibitory drug is solubilized at least in part by an ophthalmically acceptable solubilizing agent.

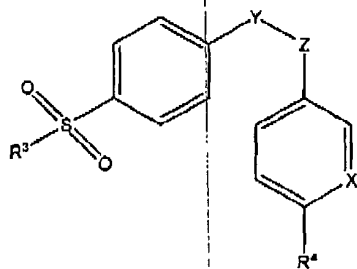
20. (original) The composition of Claim 19 wherein the solubilizing agent is a cyclodextrin.

21. (original) The composition of Claim 19 wherein the solubilizing agent is polyethylene glycol.

22. (original) The composition of Claim 10 comprising from about 0.01% to about 50% by weight of valdecoxib, from about 0.05% to about 10% by weight of carrageenan, and from about 0.5% to about 20% by weight of hydroxypropyl β -cyclodextrin.

Serial No. 09/904,098
 Attorney Docket No. 3351/2/US
 HDP Ref. No. 6794-100135/US

23. (Currently Amended) A method of treating ~~[[and/]]~~ or preventing a COX-2 mediated ophthalmic disease or disorder in an eye of a mammalian subject, the method comprising administering in each of one or more topical applications to the eye of a patient in need thereof a therapeutically or prophylactically effective amount of a composition comprising a selective COX-2 inhibitory drug or a salt or prodrug thereof and one or more ophthalmically acceptable excipient ingredients that reduces the rate of removal of the composition from the eye by lacrimation such that the composition has an effective residence time in the eye of about 2 to about 24 hours, wherein the selective COX-2 inhibitory drug is a compound having the formula:



where R³ is a methyl, amino or imide group, R⁴ is hydrogen or a C₁₋₄ alkyl or alkoxy group, X is N or CR⁵ where R⁵ is hydrogen or halogen, and Y and Z are independently carbon or nitrogen atoms defining adjacent atoms of a five- to six-membered ring that is unsubstituted or substituted at one or more positions with oxo, halo, methyl or halomethyl groups; and the composition being is in the form of an in situ gellable solution, suspension or solution/suspension having ophthalmically compatible pH and osmolality and containing a carrageenan.

24. (original) The method of Claim 23 wherein the mammalian subject is a human subject.

Claim 25 (canceled).

Serial No. 09/904,098
Attorney Docket No. 3351/2/US
HDP Ref. No. 6794-100135/US

26. (currently amended) The method of Claim ~~[[25]]~~ 23 wherein the five-to six-membered ring is selected from the group consisting of: cyclopentenone, furanone, methylpyrazole, isoxazole and pyridine rings substituted at no more than one position.

27. (original) The method of Claim 24 wherein the selective COX-2 inhibitory drug is selected from the group consisting of: celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl) phenyl]-1-one, (S)-6,8-dichloro-2-(trifluoromethyl) - 2H-1benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.

Claims 28-46 (canceled).